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IPSOLON LLP 111 SW COLUMBIA SUITE 710 PORTLAND, OR 97201			GLASS, RUSSELL S	
			ART UNIT	PAPER NUMBER
			3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/067,493

Applicant(s)

MOK ET AL.

Examiner

Russell S. Glass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 35, 36, 71, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, the rejected claims generally disclose a remote system and method for taking DNA samples with a biosensor, said biosensor presumably forming some sort of analysis on DNA sample. Such a system and method is currently unknown to one skilled in the art and furthermore is not enabled by the disclosure of this invention.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 35, 36, 71, and 72 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. In particular, the rejected claims generally disclose a remote system and method for taking DNA samples with a

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biosensor, said biosensor presumably forming some sort of analysis on DNA sample.

Such a system and method is currently unknown to one skilled in the art and

furthermore is not enabled by the disclosure of this invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**3. Claims 1-8, 11-21, 28, 30-34, 37-44, 47-57, 64, 66-70 are rejected under 35**

**U.S.C. 102(e) as being anticipated by Goldenberg, (U.S. Pub. 2002/0065682).**

**4. As per claims 1 and 37, Goldenberg discloses a health-care system and method comprising:**

a processing machine, (Goldenberg, Abstract; Figs. 1, 2; ¶ 19, 20, 40, 41);

a plurality of biosensors respectively equipped to individuals, (Goldenberg,

Abstract; Figs. 1, 2; ¶ 19, 20, 40, 41); each of the biosensors being operable to

gather information regarding physiological parameters of the respective

individuals, (Goldenberg, Abstract; Figs. 1, 2; ¶ 19, 20, 40, 41); and

relay the information to the processing machine over a network, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶ 19, 20, 40, 41, 57-64); and

data links provided from the processing machine to respective providers of a plurality of different health-care services to allow the transmission of instructions over the network for appropriate action to be taken in response to a determination that an individual is likely to suffer from a medical condition, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶ 33, 35, 62-64).

5. As per claims 2 and 38, Goldenberg discloses a system and method further comprising a first terminal connected to the processing machine and operable to present information received from one or more of the biosensors to allow the determination of whether the individual associated with the one or more biosensors is likely to suffer from a medical condition, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶ 33, 35, 62-64).

6. As per claims 3, 4, 39 and 40, Goldenberg discloses a system and method wherein at least some of the data links comprise links over the network, wherein the network is the Internet, (Goldenberg, ¶ 29).

7. As per claims 5 and 41, Goldenberg discloses a system and method wherein the network comprises a wireless network, (Goldenberg, ¶ 9, 58).

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8. As per claims 6 and 42, Goldenberg discloses a system and method wherein the processing machine is operable to transmit instructions to at least one health-care service in response to the receipt of information indicating that at least one of the physical parameters of an individual with which one of the biosensors is associated is outside predetermined limits, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶ 33, 35, 62-64).

9. As per claims 7 and 43, Goldenberg discloses a system and method further comprising a delivery device operable to administer automatically a dose of a substance to an individual, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶ 33, 35, 62-64).

10. As per claims 8 and 44, Goldenberg discloses a system and method wherein the delivery device is controllable by the processing machine, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶ 29).

11. As per claims 11 and 47, Goldenberg discloses a system and method further comprising a database storing medical records of at least some of the individuals, (Goldenberg, Fig. 7; ¶ 55, 56).

12. As per claims 12 and 48, Goldenberg discloses a system and method wherein the processing machine is operable to update the database following the receipt of information from one of the biosensors, (Goldenberg, Fig. 7; ¶ 55, 56).

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13. As per claims 13 and 49, Goldenberg discloses a system and method wherein the processing machine is operable to present at least some of the records relating to an individual along with data received from a biosensor relating to that individual, (Goldenberg, Fig. 7; ¶ 55, 56).

14. As per claims 14 and 50, Goldenberg discloses a system and method wherein the processing machine is operable to allow real-time consultation over the network between one of the individuals and a health-care expert, (Goldenberg, ¶ 10).

15. As per claims 15 and 51, Goldenberg discloses a system and method wherein the processing machine is operable to allow at least one further party to join the real-time consultation, (Goldenberg, ¶ 10).

16. As per claims 16 and 52, Goldenberg discloses a system and method wherein the real-time consultation comprises video conferencing, (Goldenberg, ¶ 9, 10. 61).

17. As per claims 17 and 53, Goldenberg discloses a system and method wherein the individuals are selected from the group comprising: health-care users, out-patients, in-patients and intensive care patients, (Goldenberg, Abstract).

18. As per claims 18, 19, 54 and 55, Goldenberg discloses a system and method further comprising a personal data storage unit associated with one of the individuals

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operable to receive and store data from a biosensor, (Goldenberg, ¶¶ 63, 64) (disclosing treatment device for receiving, analyzing and sending medical treatment information that is considered to include a storage device or medium).

19. As per claims 20 and 56, Goldenberg discloses a system and method wherein the personal data unit is used to identify an individual to a biosensor before the biosensor gathers the information from the individual, (Goldenberg, Fig. 1; ¶¶ 40, 42).

20. As per claims 21 and 57, Goldenberg discloses a system and method wherein the plurality of biosensors are operable to gather information on selected physiological parameters in dependence upon the identity of an individual, (Goldenberg, Fig. 1; ¶¶ 27, 40, 42).

21. As per claims 28 and 64, Goldenberg discloses a system and method wherein the portable processing device is operable to analyze data received from the personal data storage unit to determine whether at least one of the physical parameters of an individual with which one of the biosensors is associated is outside predetermined limits, (Goldenberg, ¶¶ 55, 63, 64) (disclosing treatment device for receiving, analyzing and sending medical treatment information that is considered to include a storage device or medium).



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22. As per claims 30 and 66, Goldenberg discloses a system and method wherein the health-care services are selected from the group comprising: a pharmacy, a physician, an emergency service; a medical hardware supplier; a nutritionist; a source of health-care information; a health-care related government body; a nursing care centre; a research facility; a health insurance broker; and a financial institution, (Goldenberg, Abstract, ¶¶ 54-56)(disclosing a physician).

23. As per claims 31 and 67, Goldenberg discloses a system and method wherein one of the health-care services comprise a source of medical records having features selected from the group comprising bio-data, health-care records, a health-care calendar, and a financial calendar, (Goldenberg, Abstract, ¶ 59)(disclosing bio-data such as vital signs).

24. As per claims 32 and 68, Goldenberg discloses a system and method wherein the processing machine is operable to transmit information regarding a condition that an individual has or is likely to develop to the individual, (Goldenberg, Abstract; Figs. 1, 2, 8; ¶¶ 33, 35, 62-64).

25. As per claims 33 and 69, Goldenberg discloses a system and method wherein the information is relayed to the processing machine over the network in an encrypted form, the encryption being specific to the individual to whom the information relates, (Goldenberg, Fig. 1; ¶ 40).

26. As per claims 34 and 70, Goldenberg discloses a system and method wherein an individual has an identification number and the gathered information for the individual is encrypted with the identification number into a data packet for decryption by the processing machine, (Goldenberg, Fig. 1; ¶ 40, 42).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. **Claims 9, 10, 22, 23, 25, 27, 45, 46, 58, 59, 61, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg in view of Nelson et al., (U.S. 6,418,346).**

28. As per claims 9 and 45, Goldenberg fails to disclose a system and method further comprising a location tracking device associated with one of the individuals, to track the location of the individual. However, such claimed systems and methods are well-known in the art as evidenced by Nelson, (Nelson, col. 4, line 50-col. 5, line 19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Goldenberg and Nelson. The motivation would have been to enhance remote monitoring of medical devices on a chronic basis to deliver clinical therapy in real-time, (Nelson, Abstract).

29. As per claims 10 and 46, Goldenberg fails to disclose a system and method wherein instructions transmitted over the network to a health-care service include the location of an individual. However, such claimed systems and methods are well-known in the art as evidenced by Nelson, (Nelson, col. 4, line 50-col. 5, line 19).

The statement of obviousness and motivation to combine Goldenberg with Nelson is as provided in the rejection of claims 9 and 45 and is incorporated herein by reference.

30. As per claims 22 and 58, Goldenberg fails to disclose a system and method wherein records relating to the individual are stored on the personal data storage unit. However, such claimed systems and methods are well-known in the art as evidenced by Nelson, (Nelson, Abstract; Fig. 5; col. 7, line 15-col. 8, line 47).

The statement of obviousness and motivation to combine Goldenberg with Nelson is as provided in the rejection of claims 9 and 45 and is incorporated herein by reference.

31. As per claims 23 and 59, Goldenberg fails to disclose a system and method

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wherein the personal data storage unit allows access to a database on which medical records relating to the individual are stored. However, such claimed systems and methods are well-known in the art as evidenced by Nelson, (Nelson, Abstract; Fig. 5; col. 7, line 15-col. 8, line 47).

The statement of obviousness and motivation to combine Goldenberg with Nelson is as provided in the rejection of claims 9 and 45 and is incorporated herein by reference.

32. As per claims 27 and 63, Goldenberg fails to disclose a system and method further comprising a portable processing device, wherein the personal data storage unit is operable to transfer data stored therein to the portable processing device. However, such claimed systems and methods are well-known in the art as evidenced by Nelson, (Nelson, Fig. 4, col. 7, line 45-67; col. 13, lines 11-38).

The statement of obviousness and motivation to combine Goldenberg with Nelson is as provided in the rejection of claims 9 and 45 and is incorporated herein by reference.

33. As per claims 25 and 61, Goldenberg fails to disclose a system and method wherein the personal data storage unit is operable to connect to the network by a wireless connection or by a contact connection. However, such claimed systems and methods are well-known in the art as evidenced by Nelson, (Nelson, Fig. 4, col. 7, line 45-67; col. 13, lines 11-38).

The statement of obviousness and motivation to combine Goldenberg with Nelson is as provided in the rejection of claims 9 and 45 and is incorporated herein by reference.

**34. Claims 24, 26, 29, 60, 62, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg in view of Snowden et al., (U.S. Pub. 2002/00226332).**

35. As per claims 24 and 60, Goldenberg fails to disclose a system and method wherein the personal data storage unit is programmed to allow access to selected portions of medical records of the individual to selected entities. However, such claimed systems and methods are well-known in the art as evidenced by Snowden, (Snowden, Abstract; ¶ 77-79) (disclosing patient-controlled access to selected portions of medical records medical records).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Goldenberg and Snowden. The motivation would have been to create a secure repository for personal medical records accessible in selected parts over secure lines, (Snowden, Abstract).

36. As per claims 26 and 62, Goldenberg fails to disclose a system and method wherein the personal data storage unit comprises a smart card. However, such claimed

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systems and methods are well-known in the art as evidenced by Snowden, (Snowden, Abstract, ¶ 105).

The statement of obviousness and motivation to combine Goldenberg with Snowden is as provided in the rejection of claims 24 and 60 and is incorporated herein by reference.

37. As per claims 29 and 65, Goldenberg fails to disclose a system and method wherein, the access of the selected entities to the selected portions of the records expires after a predetermined period. However, such claimed systems and methods are well-known in the art as evidenced by Snowden, (Snowden, 105-109) (disclosing emergency access of patient records by emergency health personnel wherein it would be obvious that the permission for access would expire after the emergency was over).

The statement of obviousness and motivation to combine Goldenberg with Snowden is as provided in the rejection of claims 24 and 60 and is incorporated herein by reference.

**38. Claims 35, 36, 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg in view of Lockhart et al., (U.S. 6,040,138).**

39. As per claims 35, 36, 71 and 72, Goldenberg fails to disclose a system and method wherein at least one of the biosensors comprises a microarray, and wherein at least one of the biosensors is operable to obtain a DNA sample from an individual.

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However, such claimed systems and methods are well-known in the art as evidenced by Lockhart, (Lockhart, Abstract; col. 2, line 35-col. 8, line 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Goldenberg and Lockhart. The motivation would have been to detect target nucleic acid sequences in the DNA sample, (Lockhart, Abstract).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is as follows: Warkentin et al., (6,471,645).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell S. Glass whose telephone number is 571-272-3132. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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5/13/2006

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PATENT EXAMINER